Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014

Message Text

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PAGE 01 TOKYO 10653 120910Z
ACTION COME-00

INFO OCT-01 EA-12 ISO-00 EB-08 OES-07 CIAE-00 INR-10
NSAE-00 L-03 /041 W
----------030452 121216Z /64
R 120857Z JUN 78
FM AMEMBASSY TOKYO
TO SECSTATE WASHDC 8736

UNCLAS TOKYO 10653

PASS USDOC

E.O. 11652: NA
TAGS: ETRD, JA
SUBJECT: TRADE FACILITATION COMMITTEE CASE - CONCEPT INC.

REF: STATE 135658

1. SUMMARY: IN ORDER TO DETERMINE WHETHER TO SUBMIT CONCEPT INC.'S CASE TO TFC, THE EMBASSY DICUSSED SUBJECT WITH THE EVALUATION AND REGISTRATION DIVISION, PHARMA-CEUTICAL AFFAIRS BUREAU, JAPANESE MINISTRY OF HEALTH AND WELFARE (MHW). WE CONCLUDE THAT, AT THIS STAGE, THIS IS NOT APPROPRIATE CASE FOR TFC CONSIDERATION. END SUMMARY.

2. CONCEPT INC. CASE CENTERS ON ISSUE OF WHETHER APPOINT-MENT BY A U.S. MANUFACTURER OF A NEW AGENT REQUIRES THAT PRODUCTS BE RETESTED IN ORDER TO BE SOLD IN JAPANESE MARKET. MHW INFORMS EMBASSY THAT SUCH RETESTING IS NOT REQUIRED PROVIDED THAT (1) THE PRODUCTS TO BE IMPORTED BY THE NEW AGENT ARE THE SAME MODELS AS THOSE TESTED BEFORE, AND (2) THE NEW AGENT CAN OBTAIN THE PREVIOUS TEST REPORTS FOR SUBMISSION TO MHW. HOWEVER, MHW POINTED OUT THAT IT IS INCUMBENT ON NEW AGENT TO OBTAIN THE TEST RESULTS FROM PREVIOUS AGENT FOR SUB-
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MISSION; MHW CANNOT REFER TO TEST RESULTS IN MHW FILES AS THIS APPLICATION IS UNDER NAME OF OLD AGENT, WHICH IS TREATED AS CONFIDENTIAL MATERIAL BETWEEN MHW AND PREVIIYS AGENT. THE APPLICATION PROCEDURE, IN THIS CASE, IS TO TRANSFER LEGAL RESPONSIBILITY OF THE PRODUCT FROM ONE JAPANESE AGENT TO ANOTHER, AND NEW AGENT MUST THEN OBTAIN TEST RESULTS FROM OLD AGENT OR FROM U.S. MANU-

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FACTURER IF IT HAS A COPY AVAILABLE.
3. THE EMBASSY HAS LEARNED FROM THE NEW AGENT, KEISEI MEDICAL, THAT THE FIRM HAS NOT YET SUBMITTED ITS IMPORT APPLICATION WITH GOJ AUTHORITIES. THE FIRM STATED THAT IT IS STILL WAITING FOR THE SHIPMENT OF THE PRODUCTS IN QUESTION FROM CONCEPT INC. AS TO WHETHER KEISEI MEDICAL WILL APPROACH PREVIOUS AGENT FOR COPIES OF TEST RESULTS, IT INFORMS EMBASSY THAT IT WILL CONSULT DIRECTLY WITH CONCEPT INC. ON BEST COURSE OF ACTION. MHW ASSURED THE EMBASSY THAT IT WILL PROVIDE EVERY POSSIBLE ASSISTANCE TO PROCESS THE APPLICATION AS EXPEDITIOUSLY AS POSSIBLE WITHIN THE FRAMEWORK OF THE LAW. MHW FURTHER STATED THAT IT WOULD BE WILLING TO DISCUSS THE CASE WITH KEISEI MEDICAL EVEN BEFORE FORMAL APPLICATION IS FILED.

4. COMMENT: THE EMBASSY DOES NOT BELIEVE THAT, AT THIS STAGE, THIS CASE IS APPROPRIATE FOR TFC CONSIDERATION. IF, HOWEVER, KEISEI MEDIAL IS UNABLE TO OBTAIN PREVIOUS TEST RESULTS, CASE SHOULD BE AGAIN REVIEWED FOR POSSIBLE SUBMISSION TO TFC. BEFORE ANY SUCH SUBMISSION, IT IS IMPORTANT FOR US TO KNOW USG PRACTICE IN SIMILAR SITUATION, I.E., DOES FDA CONSIDER TEST RESULTS AS CONFIDENTIAL AND NOT RELEASABLE TO OTHER THAN APPLICANT WHO ORIGINALLY SUBMITTED DATA. WOULD APPRECIATE CLARI-FICATION.

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Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
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Review Withdrawn Fields: n/a
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Secure: OPEN
Status: NATIVE
Subject: TRADE FACILITATION COMMITTEE CASE - CONCEPT INC.
TAGS: ETRD, JA
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